DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 25, 2014

Cooper Surgical Inc.
c/o Tim M. Lohnes
Senior Regulatory Consultant
Orchid Design
80 Shelton Technology Center
Shelton, CT 06484

Re: K141523
Trade/Device Name: Ally Uterine Positioning System™
Adapter Drape for the Ally Uterine Positioning System™
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Dated: October 17, 2014
Received: October 20, 2014

Dear Tim M. Lohnes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141523

Device Name
Ally Uterine Positioning System™

Indications for Use *(Describe)*

The Ally Uterine Positioning System™ (Ally UPS) is intended to assist the surgical staff in mounting, positioning, and holding uterine manipulators during gynecological laparoscopic procedures. It is intended for use by trained operating room personnel in an operating room environment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141523

Device Name
Adapter Drape for the Ally Uterine Positioning System™

Indications for Use *(Describe)*

The Adapter Drape for the Ally Uterine Positioning System™ (Ally UPS) is intended to assist the surgical staff in mounting, positioning, and holding uterine manipulators during gynecological laparoscopic procedures. It is intended for use by trained operating room personnel in an operating room environment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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7. 510(K) SUMMARY:

510(k) Summary of Safety and Effectiveness, (21 CFR 807.92):

Submitter:	Cooper Surgical Inc., 75 Corporate Drive, Trumbull, CT 06611
Contact Person:	Tim M. Lohnes Senior Regulatory Consultant, Orchid Design Phone: (203) 922 0105 Fax: (203) 922 0130 tim.lohnes@orchid-ortho.com
Date Prepared:	November 20, 2014
Name of Device::	Cooper Surgical ALLY Uterine Positioning System™ (UPS)
Common/Usual Name:	Holder, Manipulator, Positioner, Arm
Classification Name:	Unclassified
Device Class:	Class II
Product Code:	LKF
Predicate Device(s):	Intuitive Surgical "Probe Holder System, K071405

Device Description;

The Cooper Surgical ALLY Uterine Positioning System™ (UPS) consists of a single multi-segmented, articulated Arm that attaches to a standard OR bed rail and a separate, sterile distal adapter to accommodate a uterine manipulator. When unlocked, the articulation of the Arm allows the attached manipulator to be positioned by the user. The Arm is then locked in the desired position by depressing a foot pedal, activating a linear actuator which applies tension to an internal cable, drawing the segments together and locking the Arm.

The segmented design of the Arm allows lateral/medial movement from a single point, allowing the System to be attached to one side of the OR table.

The ALLY Uterine Positioning System™ (UPS) is not intended for patient contact. The Adapter Drape for the ALLY Uterine Positioning System™ (UPS) is provided sterile (sterilized by ethylene oxide).

(Device Description, cont.)
The ALLY UPS Adapter Drape secures either the Cooper Surgical RUMI II Uterine Manipulator Handle or the Advincula Arch Uterine Manipulator Handle to the distal end of the ALLY Arm. After attaching the Adapter, the sterile Drape is deployed to cover the non-sterile ALLY UPS Arm, maintaining the sterile field and protecting the Arm from contamination during the procedure.

Indications for Use:

ALLY Positioning System;
The ALLY Uterine Positioning System™ (UPS) is intended to assist the surgical staff in mounting, positioning and holding uterine manipulators during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.

ALLY Adapter Drape:
The Adapter Drape for the ALLY Uterine Positioning System™ (UPS) is intended to assist the surgical staff in mounting, positioning and holding uterine manipulators during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.

Comparison of Technological Characteristics with the Predicate Device:

Attribute	**ALLY Uterine Positioning System™ (UPS)**	**Intuitive Surgical "Probe Holder System, K071405**	**Determination**
Body Contact Type	Non-Patient Contact	Non-Patient Contact	Substantially Equivalent
Material(s)	Stainless steel, aluminum	Stainless steel, aluminum	Substantially Equivalent
Environment	Operating room	Operating room	Substantially Equivalent
Indications for Use, **ALLY Positioning System**	The ALLY Uterine Positioning System™ (UPS) is intended to assist the surgical staff in mounting, positioning and holding uterine manipulators during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.	The Probe Holder System is intended to assist the surgical staff in mounting, positioning and holding a uterine manipulator during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment	Substantially Equivalent

Indications for Use, **ALLY Adapter Drape**	The Adapter Drape for the ALLY Uterine Positioning System™ (UPS) is intended to assist the surgical staff in mounting, positioning and holding uterine manipulators during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.		(Substantially Equivalent)

Attribute	**ALLY Uterine Positioning System™ (UPS)**	**Intuitive Surgical "Probe Holder System, K071405**	**Determination**
Biocompatibility	No part of the ALLY UPS is intended for patient contact. The Adapter portion of the Adapter Drape is provided sterile as it attaches to the uterine manipulator within the sterile field. The Drape portion maintains sterility in the event of inadvertent patient contact, as well as protects the Arm from contamination during the procedure.	Not included in the 510(k) Summary Statement.	Substantially Equivalent
Packaging	The ALLY UPS Adapter Drape is heat-sealed in a single sterile barrier DuPont Tyvek® Pouch (Uncoated 1073B Tyvek® bonded to .0005" polyester/0.0015/0.002 LDPE). The pouches are labeled and packaged in pressboard cartons. The ALLY device and non-sterile accessories are shipped using packaging appropriate to the design and construction of the instrument to prevent damage during shipping.	The Intuitive Surgical Endoscopic Instrument Control System included a Drape, packaged in a Tyvek/polymylar peel pouch and gamma sterilized Reusable adapters are provided for Cooper Surgical uterine manipulators; specifically for the RUMI® System Uterine Manipulators RUMI® UMH600 and RUMI® Arch™ UMH700.	Substantially Equivalent

(Packaging)	This may include foam cushioned corrugated cardboard shippers, PETG, vinyl, or acrylic tubes with end caps, and 2 or 4 mil polybags for small/light weight components.	The Adapters are supplied non-sterile.	(Substantially Equivalent)
Stability/Shelf Life	The ALLY UPS Adapter Drape is sterilized by Assurance Level (SAL) of 10^{-6}, with an initial shelf life of one year.	Sterilized by end user.	Substantially Equivalent

The basis of substantial equivalence of the ALLY Uterine Positioning System™ (UPS) is the similarities in materials, design, function, performance, sterilization, and indications for use in comparison to the predicate device.

Performance Data:

The ALLY Uterine Positioning System™ (UPS) was tested in comparison to the predicate Intuitive Surgical "Probe Holder System, K071405 for;

1) Holding (locking) force

Testing also included;
1) Durability (cycle) testing
2) Handle push force
3) Drape pull off force
4) Adapter pull out force

The device is in compliance with the following standards:
IEC 60601-1 CORR 1 & 2 2007 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety

The Adapter Drape maintained its specifications for the duration of the shelf-life as demonstrated by stability testing in accordance with ASTM F1980-07.

Clinical testing was not required to support the conclusion of substantial equivalence.

Conclusion:

The substantial equivalence of the Cooper Surgical ALLY Uterine Positioning System (UPS) has been established by the similarities in design, materials, function, and Intended Use to the previously cleared Intuitive Surgical "Probe Holder System", K071405.